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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

CANELLA, KAREN A

ART UNIT	PAPER NUMBER
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1643

MAIL DATE	DELIVERY MODE
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07/12/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/764,390

Applicant(s)

RAITANO ET AL.

Examiner

Karen A. Canella

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 49, 54, 56-58, 63, 66, 72, 75, 79 and 80 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) 49, 54, 56-58, 63, 66, 72, 75, 79 and 80 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 15, 2007 has been entered.

Claim 77 has been canceled. Claims 56, 58 and 75 have been amended. Claims 49, 54, 56-58, 63, 66, 72, 75, 79 and 80 are pending and under consideration.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 49, 54, 56-58, 63, 66, 72, 75, 79 and 80 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific, substantial and credible asserted utility or a well established utility.

Claims 49 and 57 are drawn to an isolated or recombinant polypeptide comprising SEQ ID NO:3, 5 or 7, and composition thereof. Claims 75 and 77 are drawn to a method of detecting cancer in a patient comprising determining the expression level of a polypeptide comprising SEQ ID NO:3, 5 or 7. Claims 54 and 56 are drawn to a polypeptide consisting of nine, ten or fifteen contiguous amino acids of SEQ ID NO:3, 5 or 7 wherein the peptide induces a specific antibody response against a polypeptide having SEQ ID NO:3, 5 or 7. The specification asserts that 254P1D6B can be used in the same manner as other tumor antigens such as PSA, because 254P1D6B is expressed in lung, ovary, prostate, pancreas and breast tissues, when said tissues are malignant (page 122). The specification sets forth the polynucleotide of 254P1D6B v.1 clone LCP-3 as encoding SEQ ID NO:3 (Figure 2A); polynucleotides of 254P1D6B v.2 as encoding SEQ ID NO:5 (Figure 2B) and 254P1D6B v.3 as encoding SEQ ID NO:7 (Figure 2C). The

specification fails to provide a nexus between the expression of 254P1D6B (SEQ ID NO:1) in cancerous lung, ovary, prostate, pancreas and breast and the expression of the individual variant sequences. The specification does not provide any objective evidence that the variant sequences can be used as markers of the cancerous state. There is no objective evidence that all the variants possess any property as reported for the 254P1D6B (SEQ ID NO:1) sequence. Further, there are no teachings for how to use the polypeptide of claims 54 and 56 if said peptides do not generate an antibody which binds a polypeptide associated with a cancerous state. There are many examples known in the art of differing expression and function between protein variants. For instance, Matsushita et al (FEBS Letters, 1999, Vol. 443, pp. 348-352) teach that latrophilins exhibit alternative splicing resulting in latrophilin-1 which is present in brain and endocrine cells, latrophilin-2 which is ubiquitous, and latrophilin-3 which is brain-specific. Singh et al (Glycobiology, 2001, Vol. 11, pp. 587-592) teach that the CD44 splice variant, CD44v, is the major PNA-binding glycoprotein in colon cancer cells in contrast to standard CD44. Zwhalen et al (International Journal of Cancer, 2000, vol. 88, pp. 66-70) teach the expression of p73 splice variants in ovarian adenomas to the exclusion of wild-type p73. These references serve to demonstrate that one of skill in the art cannot anticipate the biological activity or tissue distribution of protein variants based on the biological activity or tissue distribution of the wild-type protein or a single protein isoform. Therefore the specification is lacking a specific, and substantial utility for the variant sequences because the utility as set forth in the specification for SEQ ID NO:1 cannot be translated into the same utility for the variant sequences.

Claims 63, 66 and 72 are drawn to the polynucleotides encoding the polypeptides of SEQ ID NO:3, 5 or 7, full complements thereof; and polynucleotides comprising SEQ ID NO:2, 4 and 6. Claim 58 is drawn to a method of generating an immune response in a mammal comprising exposing cells of said mammal to a polypeptide comprising SEQ ID NO:3, 5 or 7 wherein said immune response is the activation of B cell and thus the production of antibodies. All of said claims lack utility because the proteins which are encoded by the nucleic acids and the proteins to which the immune response is directed lack utility for the reasons set forth above.

If a molecule is to be used as a surrogate for a disease state, some disease state must be identified in some way with the molecule. There must be some expression pattern that would allow the claimed polynucleotide to be used in a diagnostic manner. Many proteins are

expressed in normal tissues and diseased tissues. Therefore, one needs to know, e.g., that the claimed polynucleotide is either present only in cancer tissue to the exclusion of normal tissue or is expressed in higher levels in diseased tissue compared to normal tissue. Evidence of a differential expression might serve as a basis for use of the claimed polynucleotide as a diagnostic for a disease. However, in the absence of any disclosed relationship between the claimed polynucleotide or the protein that is encoded thereby and any disease or disorder and the lack of any correlation between the claimed polynucleotide or the encoded protein with any known disease or disorder, any information obtained from an expression profile would only serve as the basis for further research on the observation itself. "Congress intended that no patent be granted on a chemical compound whose sole 'utility' consists of its potential role as an object of use-testing." Brenner, 148 USPQ at 696. The disclosure does not present a substantial utility that would support the requirement of 35 U.S.C. §101.

The instant situation is directly analogous to that which was addressed in Brenner v. Manson, 148 U.S.P.Q. 689 (1966), in which a novel compound which was structurally analogous to other compounds which were known to possess anti-tumor activity was alleged to be potentially useful as an anti-tumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the intended definition of "useful" as it appears in 35 U.S.C. §101, which requires that an invention must have either an immediately apparent or fully disclosed "real world" utility. The court held that:

The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. . . . [u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field. . . . a patent is not a hunting license. . . . [i]t is not a reward for the search, but compensation for its successful conclusion.

The instant claims are based on protein variants of as yet undetermined function or biological significance. There is no evidence of record or any line of reasoning that would

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support a conclusion that the variants of SEQ ID NO:3, 5 and 7 were, as of the filing date, useful for the diagnosis of cancer or the generation of an immune response against a cancerous cell..

Until some actual and specific significance can be attributed to the SEQ ID NO:3, 5 and 7, or the encoding polynucleotides, one of ordinary skill in the art would be required to perform additional experimentation in order to determine how to use the claimed invention. Such a use has been determined by the courts to be a utility which, alone, does not support patentability. Since the instant specification does not disclose a credible "real world" use for the variant proteins of the instant invention, then the claimed invention as disclosed does not meet the requirements of 35 U.S.C. §101 as being useful.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 49, 54, 56-58, 63, 66, 72, 75, 79 and 80 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, substantial and credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Applicant argues that the instant SEQ ID NO:3 is the generic 2541D6B protein and that the specification is fully enabling for said protein. Applicant refers to the specification at page 82, Example 4 and figures 14-16. This has been considered but not found persuasive. The specification states that the SSH DNA sequence (Figure 1) was designated 254P1D68 and that variants of 254P1D68 were identified (Figures 2 and 3). Figure 1 indicates that the 254P1D68 is indeed SEQ ID NO:1, not as applicant contends, SEQ ID NO:3. Further, the variants of Figures 2 and 3 are SEQ ID NO:3, 5 and 7. Therefore applicants arguments as to the enablement set forth in the specification for 254P1D68 are moot for the reasons set forth below, that the function and characteristics of a protein does not provide for the same function and characteristics of isoforms or splice variants of said protein. Applicant argues that genetic variation between the sequences does not necessarily imply that each variant has a unique function. This is true,

however there is no expectation that it would have the same function as the parent protein for the reasons of record set forth above.

Applicant argues that the state of the art allows for the generation of expression data for the claimed polypeptides and therefore does not constitute undue experimentation. This is not persuasive. The issue is not how to obtain expression data, but how to use said data in a specific, and substantial utility if said data did not support the differential expression of SEQ ID NO:3, 5 and 7 or the encoding polynucleotides in the cancerous state.

All other rejections and objections as set forth or maintained in the previous Office action are withdrawn.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10-6:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571)272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Karen A. Canella/
Ph.D., Primary Examiner
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